

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION**

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

NEORA, LLC, SIGNUM BIOSCIENCES,
SIGNUM NUTRALOGIX, and
JEFFREY OLSON,

Defendants.

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Civil Action No. 3:20-cv-01979-M

**DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFF FEDERAL TRADE
COMMISSION'S MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. MINDY
KURZER AND BRIEF IN SUPPORT**

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Defendants Neora, LLC (“Neora”) and Jeffrey Olson (“Olson,” and together with Neora, “Defendants”) file this response in opposition to the Federal Trade Commission’s (“Plaintiff” or “FTC”) Motion to Exclude the Expert Testimony of Dr. Mindy Kurzer (Dkt. 177) (the “Motion”). For the reasons set forth herein, this Court should deny Plaintiff’s Motion.

I. INTRODUCTION

Defendants’ testifying expert, Dr. Mindy Kurzer, is an expert in biochemistry and physiology of nutrients and dietary supplements. Dr. Kurzer will provide this Court with the proper framework for analyzing the product claims Defendants made regarding Neora’s dietary supplement, sold under the name “EHT Brain Formula.” She also addresses material deficiencies in the testimony and opinions of the FTC’s experts, Dr. James Mastrianni and Dr. Charles Tator. Her testimony is proper expert testimony under Federal Rule of Evidence 702 because it is relevant, reliable, and will aid the Court in resolving the FTC’s product misrepresentation claims.

II. BACKGROUND

A. Dr. Kurzer’s Expert Qualifications

Dr. Kurzer is a professor of nutrition at the University of Minnesota where she has taught nutrition and performed research for thirty-three years. Expert Report of Dr. Mindy S. Kurzer,¹ PX44 at 1 (FTC MSJ App. 1360). Dr. Kurzer’s research focuses on the health effects of dietary substances and supplements. *Id.* Since beginning her position at the University of Minnesota, Dr. Kurzer has received over \$10 million in research funding as principal or co-investigator, mainly from federal sources such as the National Institute of Health and the Department of Defense. *Id.*

¹ The FTC included a copy of Dr. Kurzer’s expert report as PX44 (FTC MSJ App. 1359-1423) (Dkt. 148-1) in connection with the FTC’s Motion for Summary Judgment (Dkt. 143). Defendants cite herein to PX44 when discussing Dr. Kurzer’s qualifications and opinions.

Dr. Kurzer received her doctorate in nutrition from the University of California, Berkeley in 1984 and was awarded a NATO postdoctoral fellowship, during which she conducted research on the dietary effects on energy expenditure at Odense University in Denmark. *Id.* She then completed a postdoctoral fellowship at the University of California, San Francisco School of Medicine. *Id.*

In addition to her research and teaching, she has held two major administrative appointments at the University of Minnesota. *Id.* at 2 (FTC MSJ App. 1361). She served as the Director of the Nutrition Graduate Program for ten years. *Id.* As the Director of the Nutrition Graduate Program, she was responsible for teaching doctoral and master's students about research ethics and how to critically review scientific literature. *Id.* Currently, she is the Director of the University of Minnesota Healthy Foods, Healthy Lives Institute, which is a university center focused on encouraging research, teaching, and outreach in the areas of food safety, food policy, food security, and prevention of obesity and chronic disease. *Id.*

B. The FTC's Allegations and Testifying Experts

The FTC alleges that Defendants claim that EHT Brain Formula can prevent, reduce the risk of, or treat concussions or chronic traumatic encephalopathy ("CTE"), Alzheimer's disease, and Parkinson's disease, and that the effects are established by scientific proof. Complaint for Permanent Injunction and Other Equitable Relief (Dkt. 1) (the "Complaint"), ¶¶ 137-142. To support these allegations, the FTC designated Drs. James Mastrianni² and Charles Tator.³

² The FTC included a copy of Dr. Mastrianni's expert report as PX41 (FTC MSJ App. 1077-1118) (Dkt. 148-1) in connection with the FTC's Motion for Summary Judgment. Defendants cite herein to PX41 when discussing Dr. Mastrianni's opinions.

³ The FTC included a copy of Dr. Tator's expert report as PX42 (FTC MSJ App. 1119-1214) (Dkt. 148-1) in connection with the FTC's Motion for Summary Judgment (Dkt. 143). Defendants cite herein to PX44 when discussing Dr. Kurzer's qualifications and opinions.

Drs. Mastrianni and Tator challenge the claims purportedly made by Neora regarding EHT Brain Formula. Specifically, Drs. Mastrianni and Tator purportedly evaluated Neora's claims related to Alzheimer's and Parkinson's (Dr. Mastrianni) and concussions and CTE (Dr. Tator). PX41 at 4-7 (FTC MSJ App. 1081-1084), PX42 at 4-7 (FTC MSJ App. 1123-1126). The only document Drs. Mastrianni and Tator reviewed in evaluating the claims Neora allegedly made about EHT Brain Formula was a 2017 Nerium⁴ document entitled "EHT Age Defying supplement claims and supporting literature and data for each" (hereinafter "2017 EHT Claims Document").⁵ See PX41 at 4, Appendix B (FTC MSJ App. 1081, 1113-18), PX42 at 4-5, Appendix B (FTC MSJ App. 1123-24, 1209-14). The 2017 EHT Claims Document lists the ingredients in EHT Brain Formula, twenty-two claims that have been made about the benefits of EHT Brain Formula, and cites thirty-seven research papers supporting the structure/function and general well-being claims discussed in the document. PX44 at 5, Appendix B (FTC MSJ App. 1364, 1409-13).

The FTC's experts opine that substantiation for the claims requires scientific testing of the product in human subjects in double-blind, randomized, placebo-controlled trials. PX41 at 7 (FTC MSJ App. 1084), PX42 at 6 (FTC MSJ App. 1125). These experts also opine, based on their review of the research papers cited in the 2017 EHT Claims Documents, that there is no competent and reliable scientific evidence to support the claims that EHT Brain Formula prevents or treats Alzheimer's disease, Parkinson's disease, concussions, or CTE. *Id.*

⁴ The FTC often improperly conflates "Nerium" with "Neora." Defendants' Response to Plaintiff's Motion for Summary Judgment at 1-2 (Dkt. 226).

⁵ The 2017 EHT Claims Document is identified as NI_CID0000458 and is attached as Appendix B to the expert reports of Drs. Mastrianni and Tator.

C. Defendants' Response to the FTC's Allegations and the Rebuttal Testimony Offered by Dr. Kurzer

Defendants made general health statements about Neora's EHT Brain Formula, but do not claim that Neora's EHT Brain Formula product can prevent, reduce the risk of, or treat concussions or CTE, Alzheimer's disease, or Parkinson's disease. Indeed, as demonstrated in Defendants' opposition to the FTC's motion for summary judgment⁶ on this point, Neora's product guides and training materials specifically state that its products "are not intended to diagnose, treat, prevent or cure any disease." MSJ Response at p. 60 (App. 3002, MSJ Response Ex. 78). As to the general health claims made by Neora, there is the requisite level of substantiation. As support, Defendants rely on Dr. Kurzer's testimony.

In her expert report, Dr. Kurzer analyzes the representations made in the 2017 EHT Claims Document, noting that there are no statements, claims, or representations that Neora EHT Brain Formula prevents or treats concussions, CTE, Alzheimer's disease, or Parkinson's disease. PX44 at 5-6, 8-9 (FTC MSJ App. 1364-65, 1367-68). To the contrary, the specific claims made in the 2017 EHT Claims Documents are that EHT Brain Formula:

- “[I]ncreases brain performance and a healthy focused mind”;
- “Promotes better cognitive function”;
- “Promotes brain health”;
- “Fortifies and strengthens natural brain functions”;
- “Protects against mental decline”;
- “Sustains and enhances brain function”;
- “Improves memory and recall”;
- “Increases focus and mental alertness”;
- “Results in being more focused”;
- “Improves productivity”;
- “[K]eeps neural connections strong, leading to more robust synaptic connections”;
- “[W]orks by preserving the state of your brain's neurons”;
- “Protects and supports neuronal networking”;

⁶ References herein to “MSJ Response Ex.” and “App.” are to the exhibits and appendix Defendants submitted in connection with their Response in Opposition to the FTC's Motion for Summary Judgment (the “MSJ Response”) (Dkt. 204).

“Defends neuronal integrity”;
“Maximizes the utility of the master protein regulator PP2A”;
“[E]nsures structural integrity of neurons, which promotes stronger neuronal connections”;
“Protects and stabilizes Tau protein, so it allows for the solids to build stable foundations for microtubules”;
“Provides protection for the brain”;
“Enhances the body’s natural energy stores”;
“Results in being more energized and laser focused”;
“Boosts the body’s immune system”; and
“Reduces damage caused by inflammation.”

See id. at 3-4, Appendix B (FTC MSJ App. 1362-63, 1409-13).

As Dr. Kurzer explains, these are structure/function or general well-being claims, not claims that EHT Brain Formula prevents, treats, or cures concussions, CTE, Alzheimer’s disease, or Parkinson’s disease. Kurzer Depo. at 47:21-48:14, 70:13-22 (Ex. A at App. 49-50, 72).⁷ Against that backdrop, Dr. Kurzer challenges Drs. Mastrianni and Tator’s conclusions regarding the level of substantiation required to substantiate the actual statements contained in the 2017 EHT Claims Document, pointing out that Drs. Mastrianni and Tator confuse the requirements for health claim substantiation for drugs with the requirements for dietary supplements. PX44 at 9 (FTC MSJ App. 1368).

In preparing her expert report, Dr. Kurzer reviewed and analyzed (1) the expert reports of Drs. Mastrianni and Tator; (2) information on the formulation of the EHT Brain Formula product; (3) EHT Brain Formula’s packaging, brochure, and website; (4) the claims made in the 2017 EHT Claims Document; (5) the supporting literature referenced in the 2017 EHT Claims Document; (6) literature related to the effects of the ingredients in EHT Brain Formula on brain health, memory, and focus, energy, immune function and damage from inflammation; and (7) claims

⁷ The FTC attached a complete copy of Dr. Kurzer’s deposition transcript as Exhibit A to its Appendix in support of the Motion (Dkt. 178). Defendants cite herein to Exhibit A when referencing Dr. Kurzer’s deposition testimony.

similar to those made about EHT Brain Formula that appear on other brain health dietary supplement products in the marketplace. *Id.* at 4 (FTC MSJ App. 1363). Based on the foregoing, and for the reasons discussed in more detail in her May 18, 2022 expert report, Dr. Kurzer opines as follows:

Drs. Mastrianni and Tator's expert reports "provide no evidence to contradict the claims made by Neora LLC about their EHT Brain Formula dietary supplement"; and

The statements contained in the 2017 EHT Claims Document "are fully supported by scientific research."

Id. at 18-19 (FTC MSJ App. 1377-78).

D. The FTC's Challenge to Dr. Kurzer

Notwithstanding that this will be a bench trial, the FTC argues that this Court should exclude the expert testimony and report of Dr. Kurzer because her report offers (1) no rebuttal to the testimony of Drs. Mastrianni and Tator; (2) unreliable factual determinations that should be left to the Court; (3) irrelevant legal opinions; and (4) irrelevant opinions on claims the FTC is not challenging. Motion at 1. The FTC's arguments lack merit and mischaracterize Dr. Kurzer's opinions. Moreover, many of the arguments raised in the FTC's motions are more properly resolved at trial through cross-examination and/or rebuttal evidence. Contrary to the FTC's arguments, Dr. Kurzer offers relevant and reliable opinions that properly rebut the opinions and testimony of Drs. Mastrianni and Tator and will aid this Court in resolving this matter on the merits.

III. ARGUMENTS & AUTHORITIES

Under Federal Rule of Evidence 702, a witness who is qualified as an expert may testify in the form of an opinion or otherwise if (1) the expert's specialized knowledge will help the trier of fact to understand the evidence or determine a fact in issue, (2) the testimony is based on sufficient

facts or data, (3) the testimony is the product of reliable principles and methods, and (4) the expert has reliably applied the principles and methods to the facts of the case. Fed. R. Evid. 702. The proponent of expert testimony bears the burden of proving that such admissibility requirements are satisfied. Fed. R. Evid. 702; *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998) (burden of proof).

Under *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), trial courts hold a “gatekeeping” function to ensure that expert testimony is relevant and reliable. *Id.* at 589, 592-93; *see also Burtleson v. Tex. Dep’t of Crim. Just.*, 393 F.3d 577, 583-84 (5th Cir. 2004). “The purpose of *Daubert* is ‘to ensure that only reliable and relevant expert testimony is presented to the jury.’” *Harding v. County of Dallas, Tex.*, Civil Action No. 3:15-CV-0131-D, 2018 WL 1156561, at *1 (N.D. Tex. Mar. 5, 2018). “Most of the safeguards provided for in *Daubert* are not as essential in a case such as this where a district judge sits as the trier of fact in place of a jury.” *Gibbs v. Gibbs*, 210 F.3d 491, 500 (5th Cir. 2000); *see also Harding*, 2018 WL 1156561, at *2 (“Given that this case will be tried to the court rather than to a jury, the objectives of *Daubert* are no longer implicated.”).⁸

“The admission or exclusion of expert testimony is a matter left to the discretion of the trial court, and that decision will not be disturbed on appeal unless it is manifestly erroneous.” *Primrose Operating Co. v. Nat’l Am. Ins. Co.*, 382 F.3d 546, 563 (5th Cir. 2004). “The rejection of expert testimony is the exception rather than the rule.” *Marten Transport, Ltd. v. Plattform Advertising, Inc.*, 184 F. Supp. 3d 1006, 1009 (D. Kan. 2016) (citing Fed. R. Evid. 702 advisory committee notes). “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on

⁸ As the Fifth Circuit has stated that the objectives of *Daubert* are not implicated in a bench trial, Defendants elected not to file motions to exclude the FTC’s experts.

the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert*, 509 U.S. at 596 (citation omitted).

A. Dr. Kurzer properly rebuts the opinions and testimony of the FTC’s experts.

Drs. Mastrianni and Tator purport to challenge the claims made in the 2017 EHT Claims Document. PX41 at 4-7 (FTC MSJ App. 1081-1084), PX42 at 4-7 (FTC MSJ App. 1123-1126). Drs. Mastrianni and Tator conclude that, in order to substantiate claims that EHT Brain Formula can prevent, reduce the risk of, or treat concussions, CTE, Alzheimer’s disease, or Parkinson’s disease, there must be scientific testing of the product in human subjects in double-blind, randomized, placebo-controlled trials. PX41 at 7 (FTC MSJ App. 1084), PX42 at 6 (FTC MSJ App. 1125). Their conclusion is perplexing considering that there is no statement in the 2017 EHT Claims Document to the effect that EHT Brain Formula can prevent, reduce the risk of, or treat concussions, CTE, Alzheimer’s disease, or Parkinson’s disease. PX44 at 5-6, 8-9, Appendix B (FTC MSJ App. 1364-65, 1367-68, 1409-13). Nonetheless, Drs. Mastrianni and Tator further opine that there is no competent and reliable scientific evidence to support the claims that EHT Brain Formula prevents or treats concussions, CTE, Alzheimer’s disease, or Parkinson’s disease. PX41 at 7 (FTC MSJ App. 1084), PX42 at 6 (FTC MSJ App. 1125).

Dr. Kurzer directly rebuts Drs. Mastrianni and Tator’s characterization of the claims actually set forth in the 2017 EHT Claims Document, and explains the level of substantiation required for the claims that are made there. As Dr. Kurzer testifies, nothing in the EHT Claims Document says that the EHT Brain Formula product can be used to prevent, reduce the risk of, or treat concussions, CTE, Alzheimer’s disease, or Parkinson’s disease. PX44 at 5-6, 8-9, Appendix B (FTC MSJ App. 1364-65, 1367-68, 1409-13). Instead, as Dr. Kurzer explains, the claims made about EHT Brain Formula in the 2017 EHT Claims Document relate to structure/function and general well-being claims, which are permissible under the Food and Drug Administration’s

(“FDA”) rules for dietary supplements. . Kurzer Depo. at 47:21-48:14, 70:13-22 (Ex. A at App. 49-50, 72); PX44 at 7 (FTC MSJ App. 1366). When viewed through the proper lens, Dr. Kurzer explains that the claims actually made by Neora do not require the degree of substantiation required for drugs (as opined by Drs. Tator and Mastrianni). PX44 at 7, 9 (FTC MSJ App. 1366, 1368).

Like two ships passing in the night, the FTC argues that Dr. Kurzer does not offer an “opinion on whether Defendants had proper substantiation for the challenged claims about EHT and EHT products.” Motion, p. 4. The FTC’s argument misses the mark, and, like its experts’ opinions, is based on a flawed premise: that the 2017 EHT Claims Document actually makes the claim that EHT Brain Formula prevents, reduces the risk of, or treats concussions, CTE, Alzheimer’s disease, and/or Parkinson’s disease. As Dr. Kurzer opines, Defendants had—and continue to have—the proper substantiation for the actual claims made in the 2017 EHT Claims Document. PX44 at 18 (FTC MSJ App. 1377). Thus, Dr. Kurzer rebuts the testimony provided by Drs. Tator and Mastrianni concerning the level of substantiation required to support the claims that are set forth in the 2017 EHT Claims Document. The reason Dr. Kurzer did not respond to the level of substantiation necessary to support claims that EHT Brain Formula prevents, treats, or cures concussions, CTE, Alzheimer’s disease, and/or Parkinson’s disease is because no such claims were presented in either Dr. Mastrianni’s report or Dr. Tator’s report. If such claims had been presented, Dr. Kurzer would have addressed them. Kurzer Depo. at 53:19-59:4 (Ex. A at App. 55-61). Instead, the FTC and its experts only identified the claims in the 2017 EHT Claims Document and, as Dr. Kurzer has opined, there is significant peer-reviewed scientific evidence substantiating those claims. PX44 at 18 (FTC MSJ App. 1377).

B. The FTC improperly characterizes Dr. Kurzer's testimony regarding whether Defendants made certain claims.

The expert reports of Drs. Mastrianni and Tator do not address claims made by Defendants about EHT Brain Formula in the 2017 EHT Claims Document. In fact, as discussed above, Drs. Mastrianni and Tator's expert reports do not respond to claims that are made anywhere in the 2017 EHT Claims Document. Notably, with the exception of the 2017 EHT Claims Document, nowhere in Drs. Mastrianni and Tator's expert reports do these experts even mention any document or other material that they considered to determine what claims Neora actually does make, or previously made, about EHT Brain Formula.

The issue here is not whether these experts verified that Defendants made the claims that they were supposed to be evaluating. Rather, the issue is that the only document that these experts considered is a document that makes no claims whatsoever about EHT Brain Formula treating or preventing Alzheimer's, Parkinson's, concussions, or CTE. Nor is there anything in Drs. Mastrianni and Tator's expert reports that invalidates the claims Defendants actually do make about EHT Brain Formula in the 2017 EHT Claims Document. *See* PX44 at 9-19 (FTC MSJ App. 1368-1378). These are material deficiencies in Drs. Mastrianni and Tator's expert reports, and Dr. Kurzer will address these issues in her testimony.

C. Dr. Kurzer's testimony regarding the substantiation requirements for dietary supplements is relevant.

EHT Brain Formula is a dietary supplement. PX44 at 3 (FTC MSJ App. 1362). As stated in the Dietary Supplement Health and Education Act of 1994, the only kinds of health claims that are allowed for dietary supplements are structure/function claims, general well-being claims, and nutrient deficiency disease claims. *Id.* at 7 (FTC MSJ App. 1366). As Dr. Kurzer explains, the claims set forth in the 2017 EHT Claims Documents are structure/function and general well-being claims, which are permissible for a dietary supplement. Kurzer Depo. at 47:21-48:14, 70:13-22

(Ex. A at App. 49-50, 72). Dr. Kurzer further opines that when applying the correct requirements for health claim substantiation for dietary supplements, there is strong, reliable evidence to substantiate all of the general well-being claims made in the 2017 EHT Claims Document. PX44 at 18 (FTC MSJ App. 1377).

Drs. Mastrianni and Tator, on the other hand, confuse the requirements for health claim substantiation for drugs with the requirements for dietary supplements. *See* PX44 at 9 (FTC MSJ App. 1368). While there may be a stringent threshold for evidence supporting health claims for a drug or for food, such evidence is not required for a dietary supplement, like EHT Brain Formula. *See id.* at 7-8 (FTC MSJ App. 1366-67). Dr. Kurzer's testimony is thus not only relevant, but it is necessary to properly frame the actual claims made by Neora and to further inform the Court regarding the reasons why the FTC's proposed injunctive relief is inappropriate. Dr. Kurzer's testimony is helpful to the Court because it provides the appropriate framework for evaluating the level of substantiation required for health claims made for dietary supplements, like EHT Brain Formula.

IV. CONCLUSION

For the foregoing reasons, defendants Neora, LLC and Jeffrey Olson respectfully request that this Court deny the FTC's motion to exclude the expert testimony of Dr. Mindy Kurzer. Defendants further respectfully request that the Court grant them any such other and further relief to which they may be justly entitled.

Date: August 19, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that a true and correct copy of the above and foregoing document has been served on August 19, 2022 on all counsel of record who are deemed to have consented to electronic service via the Court's CM/ECF system.

/s/ Craig B. Florence

Craig B. Florence